

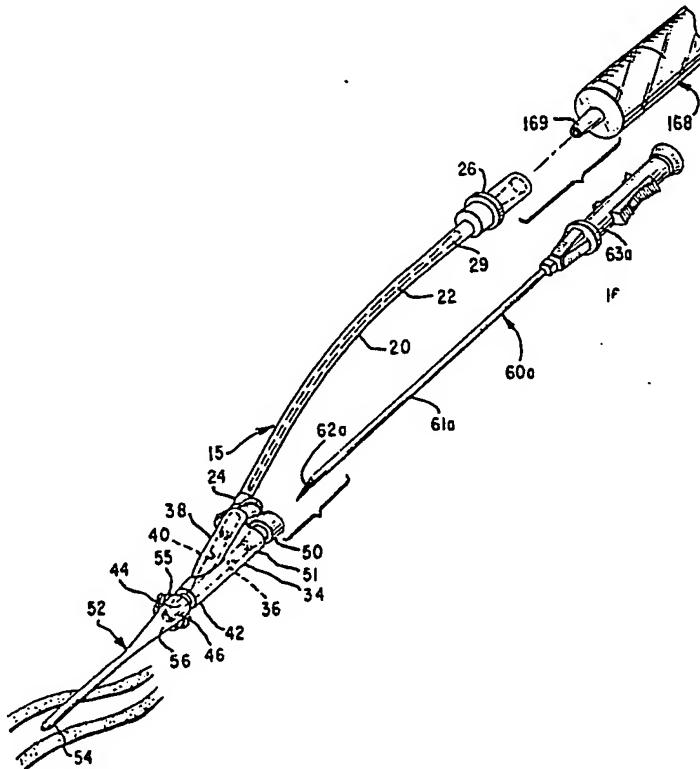
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>3</sup> :  A61M 5/00		A1	(11) International Publication Number: WO 81/01795  (43) International Publication Date: 9 July 1981 (09.07.81)
(21) International Application Number: PCT/US80/01383		(81) Designated States: AU, DE (European patent), FR (European patent), GB (European patent), JP, NL (European patent), SE (European patent).	
(22) International Filing Date: 16 October 1980 (16.10.80)			
(31) Priority Application Number: 106,493		Published <i>With international search report Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments</i>	
(32) Priority Date: 26 December 1979 (26.12.79)			
(33) Priority Country: US			
(71) Applicant: SHERWOOD MEDICAL INDUSTRIES INC. [US/US]; 1831 Olive Street, St. Louis, MO (US).			
(72) Inventor: BODICKY, Raymond, O.; 5051 Lampglow Court, St. Louis, MO (US).			
(74) Agents: RECKTENWALD, William, E., et al.; Wegner, Stellman, McCord, Wood & Dalton, 20 North Wacker Drive, Chicago, IL 60606 (US).			

## (54) Title: INJECTABLE CATHETER AND METHOD OF PLACING SAME

## (57) Abstract

A catheter introducer (15) includes a tubular component (20) with a pliable catheter (22) disposed lengthwise therein. The tubular component (20) is connected to an introducer cannula (52) that has been placed in a body passageway (65). Pressurized fluid is forced around and along the catheter (22) in the tubular component (20) to flow the catheter (22) into the body passageway (65). An enlarged proximal end (29) of the catheter (22) seats in a tapered portion (56) of the introducer cannula (52). The proximal portion (56) of the introducer cannula (52) becomes the connector for connecting the catheter (22) to an intravenous unit (70). In a modification, a Y component (32) has a needle (60a) in one leg of the Y for insertion into a body passageway (65) so that, after the needle (60a) is withdrawn, the catheter (22) may be flowed by pressurized fluid through the other leg of the Y component (32) into the body passageway. Additional modifications provide for forming the tubular component in a coil form (220) or in a U-shaped form (420). In all forms of the tubular component (20), the catheter (22) is stored in a configuration wherein no length of catheter (22) contacts any other length of the catheter (22) and the catheter is supported so as not to kink or double over during insertion.



***FOR THE PURPOSES OF INFORMATION ONLY***

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	KP	Democratic People's Republic of Korea
AU	Australia	LI	Liechtenstein
BR	Brazil	LU	Luxembourg
CF	Central African Republic	MC	Monaco
CG	Congo	MG	Madagascar
CH	Switzerland	MW	Malawi
CM	Cameroon	NL	Netherlands
DE	Germany, Federal Republic of	NO	Norway
DK	Denmark	RO	Romania
FI	Finland	SE	Sweden
FR	France	SN	Senegal
GA	Gabon	SU	Soviet Union
GB	United Kingdom	TD	Chad
HU	Hungary	TG	Togo
JP	Japan	US	United States of America

Description

Injectable Catheter and Method of Placing Same

Technical Field

5 This invention relates to a catheter and, more particularly, to a catheter introducer device using a fluid placement medium and a method of placing said catheter.

Background Art

10 This invention relates to a catheter introducer for inserting a catheter into a passageway, such as a blood vessel. A catheter so inserted is commonly used to inject an intravenous solution or to keep blood vessels free from blockage.

15 Typical prior devices have required manual manipulation using sheaths and/or gloves to thread the catheter into place. One such device is shown in the Pancy et al U. S. Patent 4,037,600, wherein a catheter is threaded through a V-shaped component after a special needle has been used to form a venipuncture. The catheter is retained in a flexible sleeve and is hand manipulated through the sleeve to thread the catheter into the passageway. The catheter must have some degree of stiffness in order to be threaded into the passageway and around bends and 20 joints in the passageway. The catheter must not be too stiff so as not to cause damage to the passageway as it is manipulated into place.

25 Other threading devices are shown in the Bennet et al U. S. Patent 3,825,001 and the Jewett U. S. Patent 3,835,854 wherein a plastic sheath

('001) for a chamber ('854) are used to store the catheter prior to and during manipulation of the catheter in place.

5 All three above-identified patents provide for inserting the catheter at a non-constant rate which increases patient discomfort.

An improved apparatus was provided by the teachings of the Smith U. S. Patents 3,703,174 and 3,826,256 wherein a very flexible catheter (wet noodle limpness) is inserted into a passageway by the use of an introducer needle and a fluid placed under pressure behind and between the juncture of the catheter and the needle cannula, which fluid propels the catheter into the passageway for a relatively great distance and at a relatively uniform rate. The catheters are stored in a coiled condition either in or out of a fluid solution such that, even though limp, the catheters have a tendency to stick together and/or to take a set creating insertion problems through the needle and threading problems in the passageway. That is, the tendency for the catheter to want to curl lengthwise causes hangups and blockages in the needle and, in the passageway, tends to curl toward the passageway wall which will slow down or stop the insertion of the catheter. Accordingly, exceptional care must be taken in manufacturing the Smith apparatus and the shelf life of the apparatus must be monitored to assure that catheters that have portions stuck together or have 30 taken a set are removed before use.

The present invention is directed to overcoming one or more of the problems as set forth above.

Disclosure of Invention

This invention relates to a catheter introducer device wherein pressurized fluid is injected into the proximal end of a relatively stiff tubular component containing the catheter, thereby moving the catheter through the tube and attached introducer cannula into a body passageway. In effect, the catheter is flowed into the passageway by the fluid flowing around and along the outer surface of the catheter. The catheter has an enlarged segment at its proximal end which prevents the catheter from being completely injected into the passageway. The enlarged segment may be formed by an extrusion process or by injection molding, or the like, and may have an eyelet inserted in the enlarged segment to prevent collapse thereof and to assist in wedging the catheter in sealing relationship in the introducer cannula. The catheter is stored in the tube in a way that prevents portions of the catheter from sticking together and prevents the catheter from kinking during insertion in a body passageway.

The device further contains a Y component which enables the lumen of the introducer cannula to receive an introducer needle, easing introduction of the introducer cannula into the passageway while also permitting the withdrawal of the needle and introduction of the catheter into the introducer cannula while maintaining a sterile condition. By

introducing the catheter and the needle through different forks of the Y component, a sterile seal may be maintained even as the needle is withdrawn from the introducer cannula and is replaced by the

5 catheter.

An improved method is disclosed for introducing a catheter into a body passageway and for connecting an I.V. unit directly to the introducer cannula.

10 The device permits quick injection of a catheter with relatively little effort, thereby minimizing patient discomfort. Further, the components of the device may be inexpensively made and easily used. The device also permits separate insertion  
15 of the needle and catheter into the introducer cannula, thus allowing use of a conventional flashback vent plug with the needle to indicate proper placement in the passageway (i.e., blood vessel) while totally eliminating the problem of the  
20 needle point cutting the catheter in the passageway.

Brief Description of Drawings

Fig. 1 is an exploded perspective view of a tubular component with a catheter therein;

25 Fig. 2 is a view showing an introducer cannula placed in a body passageway with the needle removed from the introducer cannula;

30 Fig. 3 is a perspective view of one preferred embodiment of the invention showing the tubular component and catheter connected to the introducer cannula;

Fig. 4 is an enlarged partial view of the proximal end portion of the catheter with an eyelet in place therein;

5 Fig. 5 is a perspective view of an introducer cannula, Y component and needle showing the needle and cannula penetrating into a body passageway, such as a blood vessel;

10 Fig. 6 is a partially exploded perspective view of the device of Fig. 5 after withdrawal of the needle and prior to injection of the catheter;

Fig. 7 is a perspective view of the device of Fig. 5 after the catheter has been injected into the passageway or vessel;

15 Fig. 8 is a perspective view showing the catheter as in Fig. 7 with the Y component removed, the introducer cannula backed out of the venipuncture and taped to the skin and an I.V. line connected thereto;

20 Fig. 9 is an exploded view of a modification wherein the tubular component is attached directly to the Y component;

Fig. 10 is a further modification of the tubular component; and

25 Fig. 11 is an elevational view partially in section of still another modification of the tube component.

Best Mode for Carrying Out the Invention

A catheter introducer device 15, shown in Fig. 3, consists of several separate components which are connected together for use. Fig. 1 shows

a tube or tubular component 20 with a catheter 22 disposed lengthwise and freely therein. A distal end 23 of the tubular component 20 has a male luer adapter 24 sealed thereon while the proximal end 25 has a female luer adapter 26 sealed thereon. The tubular component 20 may be made of any flexible material, but is preferably made of a transparent material, such as polyethylene, or the like. The material should be transparent or have an elongate window along the length thereof so that a user of the device can observe the discharge of the catheter 22 from the tubular component 20.

It is preferred that the catheter 22 have a lumen 21 and be made of a silicone rubber material of low reactivity, nontoxic and quite elastic. The catheter 22 has a distal end 27 which either may be rounded and closed with side ports radiating outwardly from the lumen 21 in the distal portion, or may be opened, as shown. The proximal portion 29 of the catheter 22 is flared outwardly (see Figs. 1 and 4) to form an enlarged segment 31. A fail-safe eyelet 33, preferably made of an appropriate metal, has an outwardly flared end portion 35 and an opening 37 therethrough. The opening 37 of the eyelet 33 has a diameter substantially equal to the diameter of the lumen 21 in the catheter 22. Fig. 4 illustrates a preferred location of the eyelet 33 in the proximal portion 29 of the catheter 22 wherein the flared end portion 35 of the eyelet 33 forms a support for the flared enlarged segment 31 of the catheter 22 to

prevent collapse of the segment 31. It should be noted in Fig. 4 that the outer diameter of the flared end portion 35 of the eyelet 33 is within the confines of, and is less than, the largest outside diameter of the enlarged segment 31 of the catheter 22. The outside diameter "D" of the flared enlarged segment 31 (Fig. 4) is slightly smaller than the inside diameter "E" of the passageway 39 through the male luer adapter 24 (Fig. 1) for a reason to become apparent herein-  
5 after. The tubular component 20 is shipped and stored as an individual item in the forms of invention shown in Figs. 1 through 8, 10 and 11, and, therefore, a cap 28 is fit over the male luer adapter 24 and a plug 30 is inserted in the female luer adapter 26 to  
10 retain the catheter 22 in a sterile condition in the tube or tubular component 20. A porous sealing strip 41 is provided over one opening in the end of the cap 28, which strip 41 retains the sterility of the contents of the tubular component 20, but permits  
15 air to be purged from the tubular component 20 when desired.  
20

Figs. 2 through 4 and 8 show one preferred form of the invention and the method of using same. In Fig. 2, an introducer cannula 52, of appropriate  
25 medical grade material, such as teflon, polypropylene, or the like, is shown and is comprised of an elongate, substantially straight body portion 53 with a tapered distal end portion 54 and an enlarged funnel-shaped proximal portion 56. A lumen 58 is provided length-  
30 wise of the introducer cannula 52. A hub 55 is

secured to, or molded on, the enlarged proximal portion 56 to provide a female luer adapter on the proximal portion 56 of the introducer cannula 52. An introducer needle 60 has an elongate portion 61 which 5 passes through the lumen 58 of the introducer cannula 52 with a penetrating point 62 on the distal end extending beyond the tapered distal end portion 54 of the introducer cannula 52. The introducer needle 60 may have a flashback vent plug 63 on the 10 proximal portion thereof. The distal end portion 54 is shown in Fig. 2 placed in a body passageway 65 through a venipuncture, which puncture was formed by the point 62 of the needle 60 when the needle (shown in dashed lines) was in place in the introducer cannula 52. When the penetrating point 62 15 of the introducer needle 60 is in the passageway, in this case a vein or artery, blood will flow through the needle 60 to indicate in the vent plug 63 that the needle 60 and introducer cannula 52 are 20 in the proper position. The needle 60 is now withdrawn from the introducer cannula 52 (as shown in solid lines in Fig. 2).

The tubular component 20 with the catheter 22 therein, has the plug 30 removed and a syringe 68, 25 filled with a saline solution, or the like, is connected to the female luer adapter 26. Expelling fluid from the syringe 68 into the tubular component 20 will purge the air in the tubular component 20 through the strip 41. The strip 41 prevents the 30 catheter 22 from being expelled from the tubular

component 20 as the air is being purged. The cap 28 is removed from the male luer adapter 24 of purged tubular component 20 and the needle 60 is withdrawn from the introducer cannula 52 (as shown in solid lines in Fig. 2), whereupon the male luer adapter 24 is seated in the hub 55 in the introducer cannula 52. Expelling the fluid from the syringe 68 into the tubular component 20 will force the fluid around and along the peripheral surfaces of the catheter 22 to flow the catheter 22 through the introducer cannula 52 and into the passageway 65. The enlarged segment 31 of the catheter 22 will pass through the male luer adapter 24, but will seat in the funnel-shaped proximal portion 56 of the introducer cannula 52.

The tubular component 20 and syringe 68 are disconnected from the introducer cannula 52 whereupon the introducer cannula 52 is pulled out of the venipuncture leaving the majority of the length of the catheter 22 in the body passageway 65. As shown in Fig. 8, a male luer adapter of an I.V. unit 70 is connected directly to the hub 55 on the proximal portion 56 of the introducer cannula 52 and the introducer cannula 52 is taped as by tape 59 to the area near the venipuncture. The introducer cannula 52 not only provides the structure for guiding the catheter 22 into the passageway 65, but also has the funnel-shaped proximal portion 56 serving as a locking ferrule for gripping the material of the enlarged segment 31 of the catheter

22 to form a seal therebetween. In addition, the hub 55 on the portion 56 of the introducer cannula 52 serves as a connector for connecting the I.V. unit 70, or the like, directly thereto.

5           A second preferred form of the invention is shown in Figs. 5, 6 and 7, wherein a Y-shaped component 32 is provided and has a straight leg 34 with a through passage 36 and a branch leg 38 with a passage 40. The legs 34,38 merge into a stem 42  
10 with a common passage 44 in line with the straight passage 36. A male luer adapter 46 is integrally formed on the distal end 48 of the stem 42 and a self-sealing plug 50 is attached at the proximal end 51 of the straight leg 34. The introducer cannula 52, as described with respect to Fig. 2, has the proximal portion 56 seated over the male luer adapter 46 on the Y component 32 so that the lumen 58 in the introducer cannula 52 aligns with the passages 44,36 in said Y component 32. An introducer needle 20 60a, which is substantially the same as introducer needle 60 except that it has a more elongated body portion 61a, has a penetrating point 62a and a flashback vent plug 63a. The elongate body portion 61a is of a length that when the needle 60a is  
25 inserted through the sealing plug 50 and the passages 44,36 of the Y component 32 and through the lumen 58 of the introducer cannula 52, the penetrating point 62a will project just beyond the tapered distal end portion 54 of said introducer cannula 52.

30           As shown in Fig. 5, the penetrating point 62a of the introducer needle 60a is used to make a

venipuncture into a passageway 65 in the patient with the distal end portion 54 of the introducer cannula 52 accompanying the needle 60a into the passageway 65. When the penetrating point 62a of the needle 60a is in the passageway 65, in this case a vein or artery, blood will flow through the lumen of the needle 60a and will indicate in the flashback vent plug 63a that the needle 60a and introducer cannula 52 are in the proper position.

10        The tube or tubular component 20 is then grasped and the plug 30 is removed from the one end thereof. A syringe 168, which has a male luer adapter 169 on the end thereof and which has been filled with a saline solution, or the like, is connected with the female luer adapter 26 on the tubular component 20. The plunger of the syringe 168 is depressed to purge the tubular component 20 of air in the same manner as described with respect to Fig. 3, whereupon the cap 28 is removed and the male luer adapter 24 is connected to the opening in the branch leg 38 of the Y component 32. The introducer needle 60a is now withdrawn from the Y component 32 (Fig. 6). The plunger of the syringe 168 is sharply, but firmly, depressed to expel saline solution into the tubular component 20 whereupon the fluid will flow around and along the catheter 22 to flow the catheter 22 through the tubular component 20, passages 40 and 44 of the Y component 32 and introducer cannula 52 into the passageway 65. The flared proximal portion 29 of the catheter 22 will pass through

the opening "E" in the male luer adapter 24 and through the passages 40,44 and will seat in the funnel-shaped proximal portion 56 of the introducer cannula 52. The syringe plunger can then be drawn 5 back slightly to draw blood into the catheter 22 to be sure the catheter is in the passageway and functioning properly. The Y component 32 with the tubular component 20 and syringe 168 still attached is then separated from the introducer cannula 52. The relatively straight and relatively stiff tubular component 20 assures the catheter 22 of a relatively straight storage area and a relatively straight alignment surface for introducing 10 the catheter into the passageway.

15 Once the catheter 22 is in place, the introducer cannula 52 may be withdrawn from the passageway 65 and placed so that the enlarged proximal portion or segment 29 of the catheter 22 is seated in the introducer cannula 52. The introducer cannula 20 52 is then taped to the skin, in the same manner as described with respect to Fig. 8, so as to reduce irritation to the area around the venipuncture and to assure that the distal end portion 54 of the cannula 52 does not cut the catheter 22. An I.V. 25 unit 70 may then be connected to the introducer cannula 52 in the manner described with respect to Figs. 2 through 4.

30 Fig. 9 shows essentially the same elements as shown and described in Figs. 5 through 7, with the exception that the distal end 123 of the tubular

component 120 is integrally formed with the branch leg 138 of the Y component 132. Using the modification of Fig. 9, the system is purged of air before the introducer needle 160 and introducer cannula 152 are 5 implanted in the passageway 65 of the patient. The purging takes place by depressing the plunger in syringe 268 to force solution through the tubular component 120 through the passageways 140,144 of the Y component 132 and out the introducer cannula 152. 10 Thereafter, the introducer needle 160 is pushed through the plug 150, the Y component 132 and the introducer cannula 152. The introducer needle 160 and introducer cannula 152 are inserted in the passageway 65 and the catheter 122 is injected into 15 the passageway as described above.

Fig. 10 shows another form of tubular component 220. That is, the tubular component 220 is wound in a spiral coil with mild solvent bonding being used to hold adjacent coils together. The 20 coiled configuration permits longer length catheters 222 to be used. The tubular component 220 of Fig. 8 is used to guide a catheter 222 into a passageway as described with respect to Figs. 2 through 4. Although the catheter 222 is coiled, no length of 25 the catheter is in contact with another length thereof so as to prevent the lengths of catheter from sticking together. In addition, the coils of the tubular component 220 support the catheter 222 preventing kinking of the catheter 222 in said 30 tubular component 220. Fluid expelled from a syringe

into the tubular component 220 will flow the catheter 222 out of the tubular component 220 through an introducer cannula and into a passageway.

Fig. 11 shows still a further modification 5 of the invention and, in particular, a tube or tubular component 420 is shown in a configuration with a U-shaped internal chamber 421. The tubular component 420 is closed at the proximal end 422 and has a dividing wall 423 extending from the distal end 10 424 to just short of the closed proximal end 422 so that the chamber 421 has two cavities or branches 426,427 joined at the end remote from the distal end 424. A catheter 430, of the same type and description as set out in Figs. 1 through 10, is positioned 15 in branch 426 with the flared proximal end 431 located in the vicinity of the proximal end 422 of the tubular component 420. The branch 426 of the tubular component 420 has a male luer adapter 434 which is adapted to be seated in the flared end portion 20 456 of the introducer cannula 452.

A syringe 468 is connected to a female connector 469 on the end of a flexible conduit 470. The conduit 470 is connected into an end of the branch 25 427 of the tubular component 420. The system is purged of air by depressing the plunger of the syringe 468 until the fluid of the syringe 468 flows out the male luer adapter 434. The introducer cannula 452 is inserted in the passageway 65 by means of an introducer needle, similar to introducer needle 60 30 described above, positioned in the introducer cannula

452. After the needle is removed from the introducer cannula 452, the tubular component 420 is connected to the introducer cannula 452. Depressing the plunger of the syringe 468 advances the catheter 430 from 5 the branch 426 and into the introducer cannula 452 and passageway 65. The enlarged proximal portion 431 on the catheter 430 seats in the introducer cannula 452 whereupon the tubular component 420 is disconnected from the cannula. The introducer cannula 452 10 is pulled out of the venipuncture, pulling a portion of the catheter 430 with it. The introducer cannula 452 is then taped to the skin near the venipuncture whereupon an intravenous tube or I.V. unit is attached as described above.

15 One advantage to the tubular component 420 of Fig. 11 is that the technician can hold, with one hand, both the introducer cannula 452 and the tubular component 420. The other hand is free to operate the syringe 468.

20 Other aspects, objects and advantages of this invention can be obtained from a study of the drawings, the disclosure and the appended claims.

Claims

1. A catheter placement device for propelling a flexible catheter into a passageway in a body comprising:

5 an elongate tubular means having a hollow internal cavity throughout the length thereof, said flexible catheter being disposed completely within said tubular means;

10 an introducer cannula having one end portion insertable into said body passageway;

15 means for connecting said tubular means with said introducer cannula; and

dispensing means connected to the other end of said tubular means expelling fluid into said tubular means for propelling said catheter out of 15 said tubular means and partially through said introducer cannula and partially into said body passageway.

2. A catheter placement device as claimed in claim 1 wherein said flexible catheter has an enlarged proximal portion and wherein said introducer cannula has an enlarged proximal portion whereby said enlarged proximal portion of said flexible catheter seats in the enlarged proximal portion of said cannula.

25 3. A catheter placement device as claimed in claim 1 wherein said expelled fluid from said dispensing means flows around and along said flexible catheter to flow said catheter from said tubular means into said passageway.

4. A catheter placement device as claimed in claim 1 wherein said elongate tubular means is a sleeve made of a transparent inert plastic material.

5 5. A catheter placement device as claimed in claim 4 wherein said means for connecting said tubular means with said introducer cannula is a male luer adapter sealed on the distal end of said sleeve, and wherein a female luer adapter is sealed on the proximal end of said sleeve.

10 6. A catheter placement device as claimed in claim 1 wherein said dispensing means is a syringe.

15 7. A catheter placement device as claimed in claim 1 wherein said means for connecting said tubular means with said introducer cannula is a Y component, said Y component having a stem and a pair of legs, one of said legs aligns with said stem and the other of said legs connecting with said tubular means, said stem connecting with said introducer cannula, and a needle extending through 20 said one of said legs, through said stem and through said introducer cannula, said needle and introducer cannula penetrating a wall of said body passageway to seat the distal end of said introducer cannula in said passageway.

25 8. A catheter placement device as claimed in claim 7 wherein said needle is removable from the Y component to permit the dispensing means to propel the catheter from the tubular means, through the Y component and partially through said introducer cannula and partially into said body passageway.

9. A catheter placement device as claimed in claim 7 wherein said tubular means is integrally formed with said other leg of said Y component.

10. A catheter placement device as claimed 5 in claim 7 wherein said tubular means is removably connected to said other leg of said Y component.

11. A catheter placement device as claimed in claim 1 wherein said tubular means is divided into two parallel cavities communicating with each other 10 at the proximal end thereof, one of said cavities containing said flexible catheter, a distal end of said catheter aligning with said means for connecting said tubular means to said introducer cannula, the other of said cavities being connected to said dispensing 15 means whereby fluid expelled by said dispensing means propels said catheter into said body passageway through said introducer cannula.

12. A catheter placement device as claimed in claim 1 wherein said flexible catheter has a 20 funnel-shaped proximal end portion and wherein an eyelet is seated in said funnel-shaped portion to prevent collapse of said funnel-shaped portion.

13. A catheter introducer, the improvement comprising:

25 an introducer cannula;  
a Y component having a self-sealing plug in one leg and having the stem connectable with said introducer cannula;  
an introducer needle inserted in said self- 30 sealing plug through said Y component and introducer

cannula to aid in properly positioning said cannula in a body passageway;

a tubular means connected with the other leg of said Y component;

5 a catheter in said tubular means; and  
means for dispensing fluid into said tubular means for propelling said catheter out of the tubular means, through the introducer cannula and  
10 into the body passageway after said introducer needle is withdrawn.

14. The catheter introducer of claim 13 wherein said tubular means has said catheter disposed lengthwise therein, means are disposed at the distal end of said tubular means for connecting said tubular 15 means to said other leg of said Y component, and wherein said means for dispensing fluid is connected with the proximal end of said tubular means.

15. The catheter introducer of claim 13 wherein said Y component may be removed from said 20 cannula and wherein said catheter has an enlarged segment which is seated in said cannula after said catheter is introduced into the passageway, permitting an intravenous line to be attached to said cannula.

25 16. The catheter introducer of claim 15 wherein said enlarged segment is maintained by an eyelet in the proximal end of said catheter.

17. The catheter introducer of claim 13 wherein said tubular means is coiled.

18. The catheter introducer of claim 13 wherein said tubular means is U-shaped with said 5 catheter being disposed in one leg of said "U".

19. A catheter introducer, comprising:  
a Y component having a first leg, a second leg, and a stem, said stem being connectable to an introducer cannula;  
10 a self-sealing plug receiving a needle at the first leg of said Y component;  
a tubular component with a catheter disposed lengthwise therein and having means at its distal end for connecting with the second leg of 15 said Y component; and  
means pressuring liquid into the distal end of said tubular component.

20. The catheter introducer of claim 19 wherein the means on the distal end of said tubular 20 component is a female luer adapter.

21. The catheter introducer of claim 19 wherein said tubular component is coiled.

22. The catheter introducer of claim 19 wherein the tubular component is U-shaped.

25 23. The catheter introducer of claim 19 wherein said means injecting liquid into said tubular component comprises a syringe.

24. A catheter introducer, comprising:  
a tube with a catheter disposed lengthwise  
therein;

5 means connecting the distal end of said  
tube to a body passageway;

means for injecting liquid into the  
proximal end of said tube for propelling said  
catheter from said tube and into said body passage-  
way.

10 25. The catheter introducer of claim 24  
wherein said catheter has an enlarged segment  
maintained by an eyelet seated in said proximal  
portion of the catheter.

15 26. The catheter introducer of claim 24  
wherein said tube is coiled.

27. The catheter introducer of claim 24  
wherein said tube is U-shaped.

20 28. A method of placing an elongate  
catheter contained in an elongate tubular component  
into a body passageway comprising, forming a veni-  
puncture into the body passageway using an in-  
troducer needle surrounded by an introducer can-  
nula, connecting a syringe containing a fluid to  
one end of said tubular component, purging the air  
25 from said tubular component by depressing the plunger  
of said syringe, removing the introducer needle from  
said introducer cannula to leave said introducer  
cannula in place in said passageway, connecting  
the other end of said tubular component to said  
30 introducer cannula, depressing the plunger of said

syringe to flow said catheter out of said tubular component, through said introducer cannula and into said passageway.

29. A method as claimed in claim 28 where-  
5 in the catheter has an enlarged proximal end portion which seats in said introducer cannula.

30. A method as claimed in claim 28 where-  
in said introducer cannula is connected to an I.V.  
unit to feed I.V. fluid into said passageway through  
10 said catheter.

**AMENDED CLAIMS**  
(received by the International Bureau on 6 July 1981 (06.07.81))

(amended)

1. A catheter placement device for propelling a flexible catheter into a passageway in a body comprising:

5 an elongate tubular means having a hollow internal cavity throughout the length thereof, said flexible catheter being disposed completely within said tubular means and having a longitudinal axis lying along a longitudinal axis of said tubular means;

10 an introducer cannula having one end portion insertable into said body passageway;

means for connecting said tubular means with said introducer cannula; and

15 dispensing means connected to the other end of said tubular means expelling fluid into said tubular means for propelling said catheter along the axis of said tubular means out of said tubular means and partially through said introducer cannula and partially into said body passageway.

20 2. A catheter placement device as claimed in claim 1 wherein said flexible catheter has an enlarged proximal portion and wherein said introducer cannula has an enlarged proximal portion whereby said enlarged proximal portion of said flexible catheter seats in the enlarged proximal portion of said cannula.

25 3. A catheter placement device as claimed in claim 1 wherein said expelled fluid from said dispensing means flows around and along said flexible catheter to flow said catheter from said tubular means into said passageway.



4. A catheter placement device as claimed in claim 1 wherein said elongate tubular means is a sleeve made of a transparent inert plastic material.

(amended) 5 5. A catheter placement device as claimed in claim 4 wherein said means for connecting said tubular means with said introducer cannula is a male luer adapter sealed on the distal end of said sleeve, and wherein a female luer adapter is sealed on the proximal end of said introducer cannula.

10 6. A catheter placement device as claimed in claim 1 wherein said dispensing means is a syringe.

15 7. A catheter placement device as claimed in claim 1 wherein said means for connecting said tubular means with said introducer cannula is a Y component, said Y component having a stem and a pair of legs, one of said legs aligns with said stem and the other of said legs connecting with said tubular means, said stem connecting with said introducer cannula, and a needle extending through said one of said legs, through said stem and through said introducer cannula, said needle and introducer cannula penetrating a wall of said body passageway to seat the distal end of said introducer cannula in said passageway.

25 8. A catheter placement device as claimed in claim 7 wherein said needle is removable from the Y component to permit the dispensing means to propel the catheter from the tubular means, through the Y component and partially through said introducer cannula and partially into said body passageway.

9. A catheter placement device as claimed in claim 7 wherein said tubular means is integrally formed with said other leg of said Y component.

5 10. A catheter placement device as claimed in claim 7 wherein said tubular means is removably connected to said other leg of said Y component.

10 11. A catheter placement device as claimed in claim 1 wherein said tubular means is divided into two parallel cavities communicating with each other at the proximal end thereof, one of said cavities containing said flexible catheter, a distal end of said catheter aligning with said means for connecting said tubular means to said introducer cannula, the other of said cavities being connected to said dispensing means whereby fluid expelled by said dispensing means propels said catheter into said body passageway through said introducer cannula.

20 12. A catheter placement device as claimed in claim 1 wherein said flexible catheter has a funnel-shaped proximal end portion and wherein an eyeret is seated in said funnel-shaped portion to prevent collapse of said funnel-shaped portion.

(amended) 13. A catheter introducer, the improvement comprising:

25 an introducer cannula;  
a Y component having a self-sealing plug in one leg and having the stem connectable with said introducer cannula;

30 an introducer needle inserted in said self-sealing plug through said Y component and introducer

cannula to aid in properly positioning said cannula in a body passageway;

a tubular means connected with the other leg of said Y component;

5 a flexible catheter disposed along the length of said tubular means; and

means for dispensing fluid into said tubular means for propelling said catheter out of the tubular means, through the introducer cannula and into the body passageway after said introducer needle 10 is withdrawn.

14. The catheter introducer of claim 13 wherein said tubular means has said catheter disposed lengthwise therein, means are disposed at the distal end of said tubular means for connecting said tubular means to said other leg of said Y component, and wherein said means for dispensing fluid is connected with the proximal end of said tubular means.

15. The catheter introducer of claim 13 wherein said Y component may be removed from said cannula and wherein said catheter has an enlarged segment which is seated in said cannula after said catheter is introduced into the passageway, permitting an intravenous line to be attached to said cannula.

25 16. The catheter introducer of claim 15 wherein said enlarged segment is maintained by an eyelet in the proximal end of said catheter.

(amended) 17. The catheter introducer of claim 13 wherein said tubular means is coiled and wherein said flexible catheter lies along the axis of said tubular means.

(amended) 5 18. The catheter introducer of claim 13 wherein said tubular means is U-shaped with said flexible catheter being disposed along the axis of one leg of said "U".

(amended) 10 19. A catheter introducer, comprising:  
a Y component having a first leg, a second leg, and a stem, said stem being connectable to an introducer cannula;  
a self-sealing plug receiving a needle at the first leg of said Y component;  
15 a tubular component with a flexible catheter disposed lengthwise therein and having means at its distal end for connecting with the second leg of said Y component; and  
means pressuring liquid into the distal end of said tubular component for propelling said flexible catheter along the axis of said tubular component into and partially through said introducer.

20 25 20. The catheter introducer of claim 19 wherein the means on the distal end of said tubular component is a female luer adapter.



(amended)

21. The catheter introducer of claim 19 wherein said tubular component is coiled and said flexible catheter lies along the axis of said tubular component.

5

22. The catheter introducer of claim 19 wherein the tubular component is U-shaped.

23. The catheter introducer of claim 19 wherein said means injecting liquid into said tubular component comprises a syringe.

10

BUREAU  
OMPI

(amended)

24. A catheter introducer, comprising:

a tube with a flexible catheter having a longitudinal axis disposed lengthwise along the axis of said tube;

5

means connecting the distal end of said tube to a body passageway;

means for injecting liquid into the proximal end of said tube for propelling said flexible catheter from said tube and into said body passageway.

10

25. The catheter introducer of claim 24 wherein said catheter has an enlarged segment maintained by an eyelet seated in said proximal portion of the catheter.

15

26. The catheter introducer of claim 24 wherein said tube is coiled.

27. The catheter introducer of claim 24 wherein said tube is U-shaped.

20

28. A method of placing an elongate catheter contained in an elongate tubular component into a body passageway comprising, forming a venipuncture into the body passageway using an introducer needle surrounded by an introducer cannula, connecting a syringe containing a fluid to one end of said tubular component, purging the air from said tubular component by depressing the plunger of said syringe, removing the introducer needle from said introducer cannula to leave said introducer cannula in place in said passageway, connecting the other end of said tubular component to said introducer cannula, depressing the plunger of said

25

30

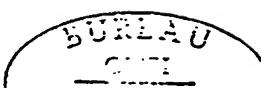
BUREAU  
OMPT

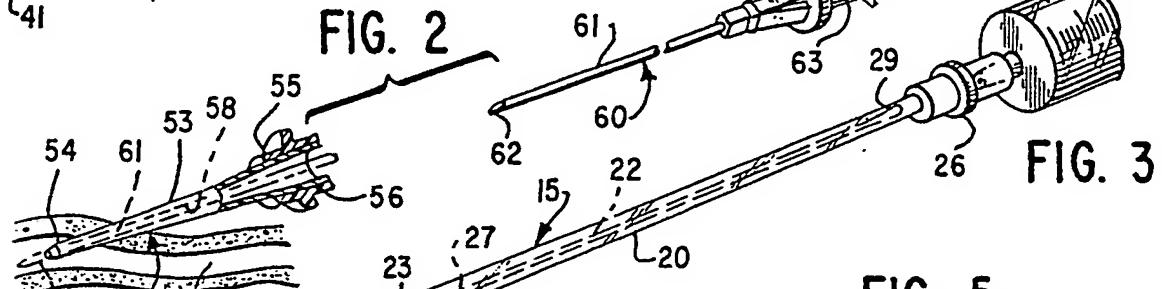
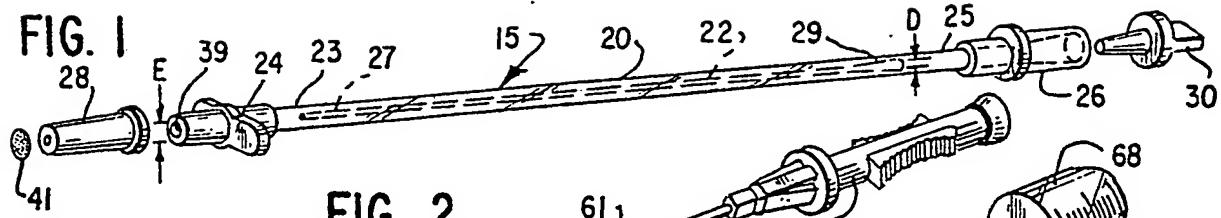
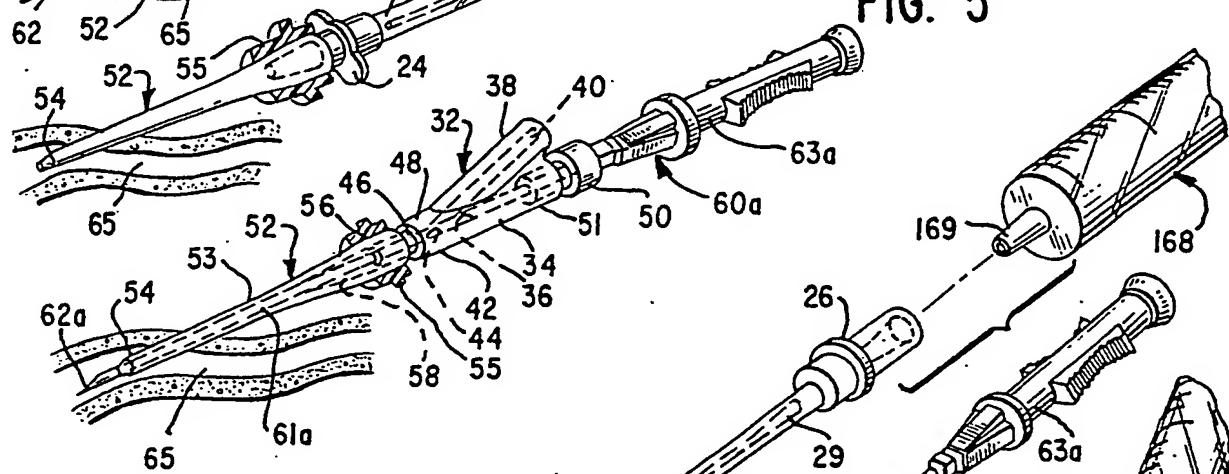
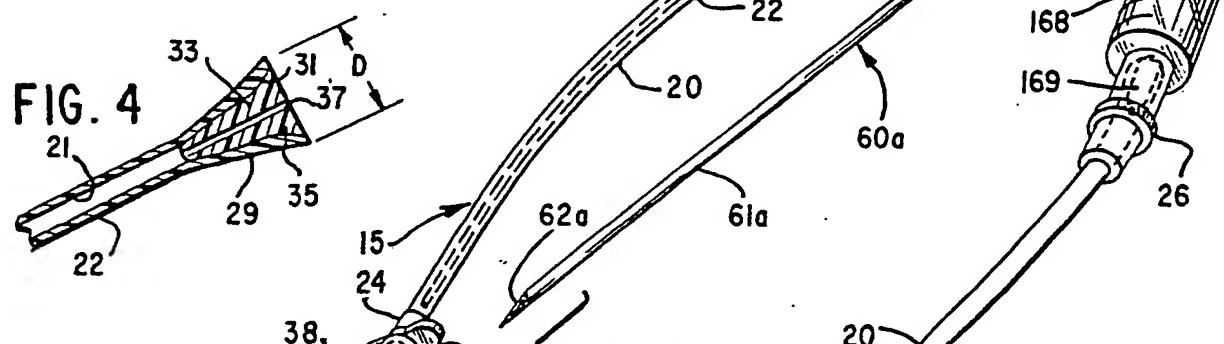
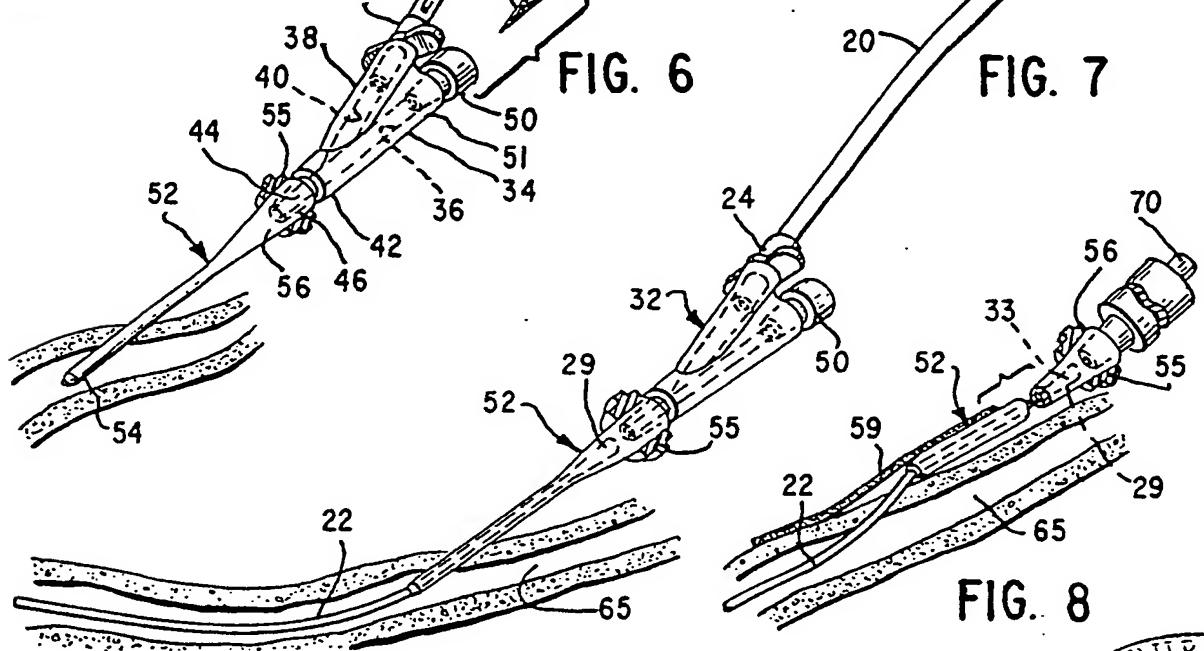
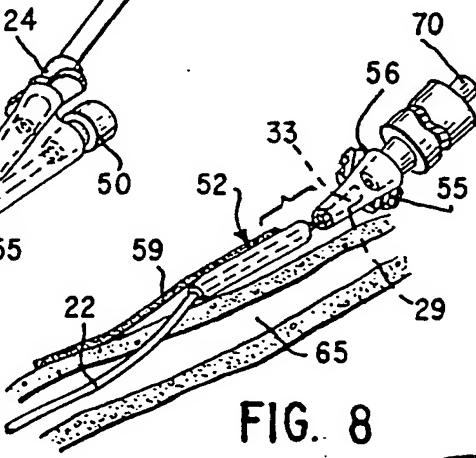
syringe to flow said catheter out of said tubular component, through said introducer cannula and into said passageway.

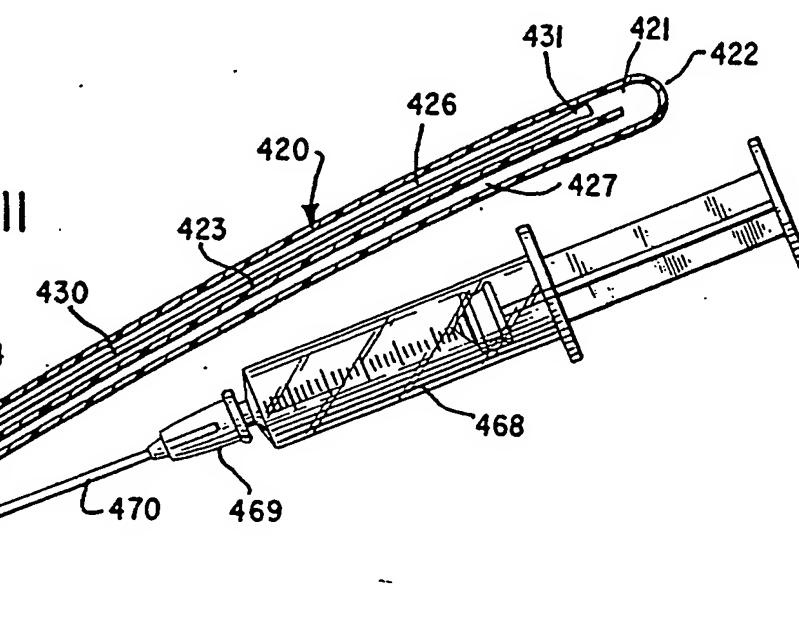
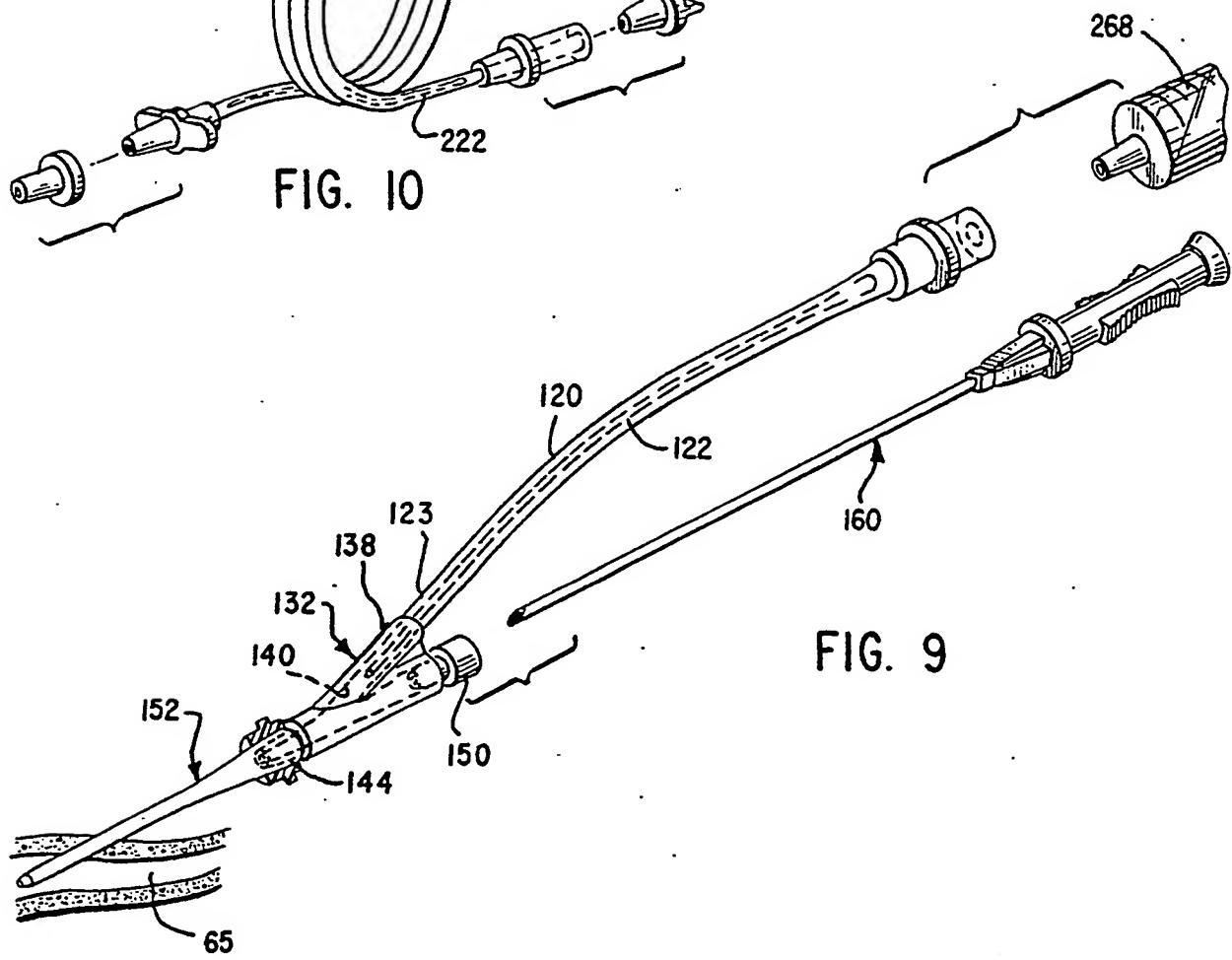
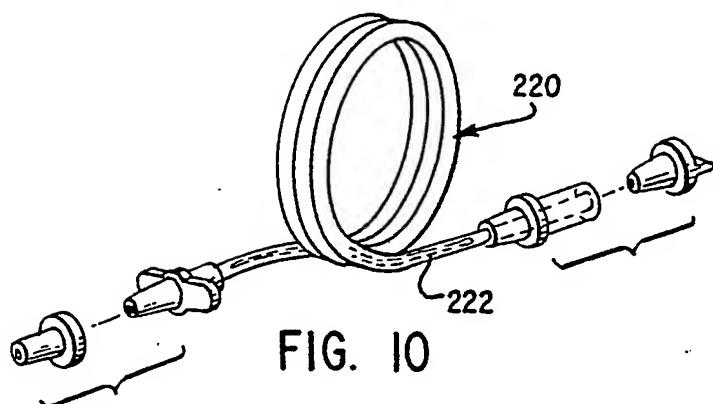
29. A method as claimed in claim 28 where-  
5 in the catheter has an enlarged proximal end portion which seats in said introducer cannula.

==

30. A method as claimed in claim 28 where-  
in said introducer cannula is connected to an I.V. unit to feed I.V. fluid into said passageway through  
10 said catheter.



**FIG. 3****FIG. 5****FIG. 6****FIG. 8**



# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US80/01383

## I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) <sup>8</sup>

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl. <sup>3</sup> A61M 5/00  
US Cl. 128/214.4

## II. FIELDS SEARCHED

Minimum Documentation Searched <sup>4</sup>

Classification System	Classification Symbols
U.S.	128/214.4, 214, 347, 348, 218, 221, 262, Dig. 16

Documentation Searched other than Minimum Documentation  
to the Extent that such Documents are Included in the Fields Searched <sup>5</sup>

## III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>14</sup>

Category <sup>15</sup>	Citation of Document, <sup>16</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No. <sup>18</sup>
X	US,A, 3,826,256, Published 30 July 1974, SMITH	1-30
X	US,A, 3,703,174, Published 21 November 1972, SMITH	1-30
X	US,A, 4,159,022, Published 26 June 1979, PEUSNER	1-30
X	US,A, 3,757,771, Published 11 September 1973 RUEGG et al	13-23
X	US,A, 4,037,600, Published 26 July 1977, PONCY et al	13-23
X	US,A, 4,099,528, Published 11 July 1978, SORENSEN et al	13-23
P	US,A, 4,205,675, Published 03 June 1980, VAILLANCOURT	1-12
X	US,A, 3,903,885, Published 09 September 1975 FUCHS	1-12
A	US,A, 3,825,001, Published 23 July 1974, BENNET et al	

(Cont. On Suppl. Sheet 2)

\* Special categories of cited documents: <sup>15</sup>

"A" document defining the general state of the art

"E" earlier document but published on or after the international filing date

"L" document cited for special reason other than those referred to in the other categories

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but on or after the priority date claimed

"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention

"X" document of particular relevance

## IV. CERTIFICATION

Date of the Actual Completion of the International Search <sup>19</sup>

13 April 1981

Date of Mailing of this International Search Report <sup>20</sup>

06 MAY 1981

International Searching Authority <sup>1</sup>

ISA/UJS

Signature of Authorized Officer <sup>20</sup>

  
SC Pellegrino

**FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET**

III

A US,A, 3,835,854, Published 17 September 1974  
JEWETT

A US,A, 4,160,951, Published 10 July 1979,  
CHITTENOEN

**V.  OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE<sup>10</sup>**

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1.  Claim numbers \_\_\_\_\_, because they relate to subject matter<sup>11</sup> not required to be searched by this Authority, namely:

2.  Claim numbers \_\_\_\_\_, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out<sup>12</sup>, specifically:

**VI.  OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING<sup>13</sup>**

This International Searching Authority found multiple inventions in this International application as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers: